

REMARKS

This application contains claims 1-155, the status of which is as follows:

(a) Claims 1-122 have been cancelled. The Applicant may prosecute these claims in the future.

(b) Claims 123-155 are new claims which find support in PCT/IL2004/001140, in accordance with the explanation below.

A first preliminary amendment was filed in this application under the assumption that certain claims had been previously amended under Article 34 of the Patent Cooperation Treaty in PCT/IL2004/001140 ("the PCT application"). In addition, other claims were cancelled to reduce excess claim fees, and still other claims were amended to remove multiple dependencies, and/or to change their dependency to a pending claim. It is currently unclear to the applicant if the Article 34 amendments were entered in the PCT application, and, furthermore, the applicant wishes to add new claims.

In order to simplify matters, all of the previously pending claims are currently being cancelled, and new claims are being added. Of the new claims, 123-144, 147-148, and 151-155 correspond to previously filed claims, and claims 145-146, and 149-150 are new claims. All of the currently pending claims find support in the corresponding PCT application, and therefore do not constitute new matter, in accordance with the table below:

Claim	Support
<p>123. Apparatus comprising: a capsule, adapted to be swallowed by a subject, and comprising:</p> <p>at least one radiation source, adapted to emit radiation having an energy of at least 10 keV; and</p> <p>at least one photon detector, adapted to detect photons generated responsively to the emitted radiation, the photons having an energy of at least 10 keV;</p> <p>a radiopaque oral contrast agent, adapted to be administered to the subject; and</p> <p>a control unit, adapted to analyze data regarding the photons in order to generate information useful for identifying a clinically-relevant feature of a gastrointestinal (GI) tract of the subject.</p>	<p>Claim 123 corresponds to claim 1 of the PCT application but has been amended to recite a radiopaque oral contrast agent. This amendment incorporates into independent claim</p> <p>1 the limitation of dependent claim 2, of the PCT application. Claim 123 additionally limits the oral contrast agent to a <i>radiopaque</i> oral contrast agent, as is supported explicitly and implicitly throughout the specification, for example:</p> <p>Figs. 2A-D are schematic illustrations of apparatus for conducting an exemplary experiment that illustrates physical principles upon which some embodiments of the present invention are based... A container 12 is filled with a radio-opaque contrast agent 10 in liquid or low viscosity gel, and a reservoir 17 is placed below the container and filled with water 11. A small water-filled balloon 18 is placed at the bottom of the container. In this experiment, container 12 filled with contrast agent 10 simulates a colon filled with contrast agent, water-filled reservoir 17 simulates tissues and organs outside the colon, and water-filled balloon 18 simulates an anatomical abnormality, such a polyp. [p. 18, lines 2-10]</p> <p>Reference is now made to Fig. 1A. During a typical screening procedure using system 40, an oral contrast agent 70 is administered to subject 54. Contrast agent 70 is typically adapted to pass through a gastrointestinal (GI) tract 72 and be expelled with the feces, substantially without being absorbed into the blood stream. The contrast agent material may be similar to compounds used routinely for the study of the GI with X-rays, such as Barium sulfate liquid concentrate, iodine-based compounds, or other such materials. For some applications, additional appropriate contrast agents include Tantalum, Gadolinium, Thorium, Bismuth, and compounds of these materials. [p. 22, lines 12-19]</p>
<p>124. The apparatus according to claim 123, wherein the agent comprises an agent having a high Z, adapted to be administered to the subject.</p>	<p>Claim 3 of the PCT application, amended to provide correct antecedent basis due to the amendment described above</p>

125. The apparatus according to claim 123, wherein the radiation source comprises a radioisotope.	Claim 6 of the PCT application
126. The apparatus according to claim 123, wherein the radiation source comprises at least one collimator, adapted to collimate the radiation emitted by the radiation source.	Claim 10 of the PCT application
127. The apparatus according to claim 123, wherein the photon detector comprises at least one collimator, adapted to collimate the photons detected by the photon detector.	Claim 11 of the PCT application
128. The apparatus according to claim 123, wherein the control unit is adapted to distinguish between gas in the GI tract and the clinically-relevant feature.	Claim 12 of the PCT application
129. The apparatus according to claim 123, wherein the control unit is adapted to analyze X-ray fluorescence (XRF) photons generated responsively to the emitted radiation.	Claim 13 of the PCT application
130. The apparatus according to claim 123, wherein the control unit is adapted to analyze X-ray fluorescence photons generated responsively to the emitted radiation, and Compton backscattered photons generated responsively to the emitted radiation.	Claim 14 of the PCT application

131. The apparatus according to claim 123, wherein the control unit is adapted to estimate a distance from a site of the capsule to a wall of the GI tract.	Claim 22 of the PCT application, amended to remove multiple dependencies.
132. The apparatus according to claim 131, wherein the control unit is adapted to analyze Compton backscattered photons generated responsively to the emitted radiation.	Claim 24 of the PCT application, amended to change dependency to a currently pending claim.
133. The apparatus according to claim 132, wherein the control unit is adapted to estimate the distance by estimating a depth of the contrast agent between the site of the capsule and the wall of the GI tract responsively to the analysis of the Compton backscattered photons.	Claim 25 of the PCT application, amended to provide correct antecedent basis due to the language of claim 123 (corresponding to claim 1 of the PCT application) described above.
134. The apparatus according to claim 131, wherein the control unit is adapted to analyze X-ray fluorescence (XRF) photons generated responsively to the emitted radiation.	Claim 27 of the PCT application, amended to change dependency to a currently pending claim.
135. The apparatus according to claim 123, wherein the radiation source is adapted to emit the radiation from the capsule only a portion of a time that the capsule is in the GI tract.	Claim 29 of the PCT application, amended to remove multiple dependencies

136. The apparatus according to claim 135, wherein the capsule comprises a sensor, adapted to sense a parameter indicative of possible imminent motion of the capsule in the GI tract, and wherein the radiation source is adapted to emit the radiation from the capsule responsively to the sensing of the parameter by the sensor.	Claim 30 of the PCT application
137. The apparatus according to claim 135, wherein the radiation source comprises a radioisotope, wherein the capsule comprises a radiation shield, and wherein the capsule comprises an actuator, adapted to move at least one of the radiation source and the shield, such that the shield does not block the radiation emitted from the radiation source during the portion of the time.	Claim 32 of the PCT application
138. The apparatus according to claim 123, wherein the capsule comprises an inflatable balloon, adapted to inflate around the capsule.	Claim 36 of the PCT application, amended to remove multiple dependencies
139. The apparatus according to claim 123, wherein the at least one photon detector comprises a plurality of photon detectors, arranged to detect photons arriving from a plurality of respective detection directions.	Claim 55 of the PCT application, amended to remove multiple dependencies

140. The apparatus according claim 123, wherein the capsule comprises at least one radiation shield.	Claim 57 of the PCT application, amended to remove multiple dependencies
141. The apparatus according to claim 140, wherein the at least one shield is configured to prevent radiation from being emitted from the radiation source in directions other than a single confined solid sector relative to a sphere surrounding the capsule.	Claim 58 of the PCT application
142. The apparatus according to claim 123, wherein the clinically-relevant feature includes a pathological abnormality of the GI tract.	Claim 63 of the PCT application, amended to remove multiple dependencies
143. The apparatus according to claim 142, wherein the pathological abnormality includes a polyp.	Claim 64 of the PCT application
144. The apparatus according to claim 123, wherein the control unit is adapted to detect that the capsule has reached an area of clinical interest within the GI tract.	Claim 69 of the PCT application, amended to remove multiple dependencies

145. The apparatus according to claim 144, wherein the control unit is adapted to withhold the emission of radiation by the radiation source until the capsule has reached the area of clinical interest.

New claim. Supported by the PCT application:

In an embodiment of the present invention, a method for detecting polyps and other anatomical deformations within the GI tract comprises: (a) placing a contrast agent within the internal space of the GI tract of a subject; (b) administering a capsule, such as capsule 50, to the subject; (c) detecting that the capsule has reached an area of clinical interest within the GI tract. For example, for detecting polyps or other anatomical deformations within the colon, the area of clinical interest is typically the colon or the lower ileum; and (d) responsively to the detection, activating the capsule. [Page 25, lines 24-30] Further alternatively, for detecting that the capsule has reached the colon, the capsule comprises a trigger that is set to switch the capsule on once it passes near an externally-fixed sticker placed on the lower abdomen near the proximity of the entrance to the colon. Such a trigger may comprise, for example, an active oscillating circuit on the sticker. As the capsule comes close to the sticker, a passive resonant circuit in the capsule draws energy from the oscillating on the sticker, and this triggers the capsule to start operating. Similar devices are commonly used in anti-theft systems in stores and libraries. [Page 27, lines 19-26]

Still further alternatively, for detecting that the capsule has reached the colon, the capsule comprises a pressure sensor that is adapted to measure pressure changes within the GI tract. As the capsule passes through the GI tract, pressure measurements are continuously monitored. In the stomach, pressure changes are generally infrequent, e.g., every few minutes. When pressure changes become more frequent and rhythmic, this may indicate that the capsule has entered into the small intestine, where it is expected to travel for 2 – 5 hours on average. Once the rhythmic pressure changes cease and less regular pressure waves and less frequent pressure waves are monitored, it is likely that the capsule has entered the large intestine where it is expected to remain for between 24 and 72 hours on average. [Page 27, line 27 to Page 28, line 3]

In an embodiment of the present invention, an energy-saving protocol is used to save battery power when the capsule is traveling in the GI tract before entering the colon. In accordance with such a protocol, one or more of the techniques described hereinabove for detecting that the capsule has reached the colon are used. Once arrival in the colon has been detected, the capsule starts data collection in order to detect polyps within the colon. This data collection typically lasts on average between 24 and 72 hours. [Page 45, lines 24-29]


146. The apparatus according to claim 145, wherein the control unit is adapted to withhold the photon detector from detecting photons, and to withhold the control unit from analyzing data, until the capsule has reached the area of clinical interest.	New claim. Supported by the PCT application using same text as indicated above for claim 145
147. The apparatus according to claim 144, wherein the control unit is adapted to detect that the capsule has reached the area by detecting and analyzing X-ray fluorescence (XRF) photons.	Claim 71 of the PCT application
148. The apparatus according to claim 144, wherein the capsule comprises a pressure sensor, and wherein the control unit is adapted to detect that the capsule has reached the area responsively to a change in pressure detected by the pressure sensor.	Claim 74 of the PCT application
149. The apparatus according to claim 148, wherein the control unit is adapted to withhold the emission of radiation by the radiation source until the capsule has reached the area of clinical interest.	New claim. Supported by the PCT application using same text as indicated above for claim 145
150. The apparatus according to claim 149, wherein the control unit is adapted to withhold the photon detector from detecting photons, and to withhold the control unit from analyzing data, until the capsule has reached the area of clinical interest.	New claim. Supported by the PCT application using same text as indicated above for claim 145
151. The apparatus according to claim 148, wherein the control unit is adapted to detect that the capsule has reached the area by detecting and analyzing X-ray fluorescence (XRF) photons, and responsively to the change in pressure.	Claim 76 of the PCT application

<p>152. The apparatus according to claim 123, wherein the capsule comprises at least one extending element, adapted, when extended, to maintain the capsule at least a certain distance from a wall of the GI tract.</p>	<p>Claim 82 of the PCT application, amended to remove multiple dependencies</p>
<p>153. The apparatus according to claim 123, wherein the capsule comprises at least one extending element, adapted, when extended, to orient a long axis of the capsule generally parallel to a longitudinal axis of the GI tract.</p>	<p>Claim 87 of the PCT application, amended to remove multiple dependencies</p>
<p>154. The apparatus according to claim 153, wherein the extending element comprises an expandable flexible chamber, wherein the flexible chamber comprises a super-absorbent hydrogel, and wherein the flexible chamber is adapted to expand when the hydrogel absorbs liquids from the GI tract.</p>	<p>Claim 89 of the PCT application, amended to change dependency to a currently pending claim</p>
<p>155. A method comprising:</p> <p>administering a radiopaque oral contrast agent to a subject;</p> <p>emitting, from within a gastrointestinal (GI) tract of the subject, radiation having an energy of at least 10 keV;</p> <p>detecting, from within the GI tract, photons generated responsively to the emitted radiation, the photons having an energy of at least 10 keV; and</p> <p>analyzing data regarding the detected photons in order to generate information useful for identifying a clinically-relevant feature of the GI tract.</p>	<p>This corresponds to claim 112 of the PCT application, but has been amended to recite administering a radiopaque oral contrast agent. This amendment incorporates into independent claim 112 the limitation of dependent claim 113 of the PCT application. Claim 155 additionally limits the oral contrast agent to a <i>radiopaque</i> oral contrast agent, as is supported explicitly and implicitly throughout the specification, for example:</p> <p>Page 18, lines 2-10</p> <p>Page 22, lines 12-19</p> <p>[These are the same citations as those used as support for claim 123.]</p>

Notice of allowance of the present application is respectfully requested.

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Respectfully submitted,

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